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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,364	06/13/2005	Shiro Shibayama	Q88494	6855

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SUGHRUE-265550  
2100 PENNSYLVANIA AVE. NW  
WASHINGTON, DC 20037-3213

EXAMINER
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MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

MAIL DATE	DELIVERY MODE
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08/13/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/538,364

Applicant(s)

SHIBAYAMA ET AL.

Examiner

Prema M. Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 9 and 33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Claims 1-8, 10-32 have been canceled (8/3/2007). Amended claim 9 (8/3/2007) and new claim 33 are pending in the instant application and are under consideration.

2. Receipt of applicant's arguments filed on 8/3/2007 is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 3/28/2007:

(i) the objection to the title of the invention;

(ii) the rejection of claim 9, under 35 U.S.C. 112, second paragraph;

Applicant's arguments with respect to claim 9 have been considered but are moot in view of the new ground(s) of rejection.

4. Applicants arguments filed on 8/3/2007 have been fully considered but were persuasive in part. The issues remaining and new issues are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim rejections-35 USC § 112, first paragraph***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6a. Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The antibodies 45531.111 and 45523.11 recited in claim 33 are essential to the claimed invention. The reproduction of antibodies from hybridomas is an extremely unpredictable event. The antibody 45531.111, for example, must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. The instant specification does not disclose a repeatable process to obtain the antibody, and it is not apparent if the antibody is readily available to the public. If the deposits have been made under the terms of the Budapest Treaty, an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the hybridomas for the antibodies have been deposited under the Budapest Treaty and that the hybridoma will be irrevocably and without restriction or condition be released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. See 37 CFR 1.808. Further, the record must be clear that the deposit will be maintained in a public depository for a period of 30 years after the date of deposit or 5 years after the last request for a sample or for the enforceable life of the patent whichever is longer. See 37 CFR 1.806. If the deposit has not been made under the Budapest treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature must be made, stating that the deposit has been made at an acceptable depository and that the criteria set forth in 37 CFR 1.801-1.809, have been met.

Amendment of the specification to disclose the date of deposit and the complete name and address of the depository is required.

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If the deposit was made after the effective filing date of the application for a patent in the United States, a verified statement is required from a person in a position to corroborate that the hybridomas or the antibodies described in the specification as filed are the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to *In re Lundak*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985), and 37 CFR 1.801-1.809 for further information concerning deposit practice.

***Claim Rejections - 35 USC § 112, second paragraph***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 9, 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 9 is rejected as vague and indefinite because claim recites “strong binding site”. “Strong” is a relative term. It is suggested that this term be deleted from the claim to obviate this rejection.

Claim 9, lines 8-9, is vague and indefinite because the claim recites that “the antibody has a property of not binding to CCR5. However, this is inconceivable because the antibody is an

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anti-CCR5 antibody. Furthermore, is this the "labeled anti-CCR5 antibody" Applicants are referring to in the claim?

Claim 9, line 9, is vague and indefinite because it recites "or an isotype control of the labeled anti-CCR5 antibody". This limitation is unclear and confusing in the claimed method. Does the antibody not bind to the isotype control of the labeled anti-CCR5 antibody? This is also inconceivable.

Claim 33 is rejected as vague and indefinite insofar as it depends on claim 9 for its limitations.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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8a. Claim 9 is rejected under 35 U.S.C. 103(a) as unpatentable over WO 98/18826 (Leucosite, Inc.)

This rejection is maintained for reasons of record set forth at pages 3-4 of the previous Office action (1/22/2007).

Applicants argue that the WO '826 patent does not disclose or suggest such a method for measuring an occupying ratio of a compound bound to a strong binding site of CCR5 and that in general, the ligand bound to the receptor is dissociated with a lapse of time. However, contrary to Applicants arguments, since the recitation of the term "strong binding site" is unclear, the reference anticipates the claim because the reference describes a method for measuring ligand binding to a cell expressing CCR5 comprising allowing a CCR5 expressing cell to contact with a labeled compound (MIP-1 $\alpha$  or MIP-1 $\beta$ ), allowing the labeled compound to bind, then contacting with anti-CCR5 antibody and calculating the binding ratio of the labeled compound bound to CCR5 based on the amount of labeled compound bound in the presence and absence of anti-CCR5 antibody (see page 64, lines 21-31; page 65, lines 1-7). The reference teaches using an anti-CCR5 antibody, which binds to CCR5 and competes against the compound for the binding site of CCR5. It would be *prima facie* obvious to one of ordinary skill in the art to measure binding of the compound bound to CCR5 on the cell based on the ratio of the bound amount of labeled anti-CCR5 antibody when the compound is bound to CCR5 to a bound amount of labeled anti-CCR5 antibody when the compound is not bound to CCR5. One of ordinary skill in the art would have been motivated to do so because the reference teaches that total binding was in the presence of labeled compound with or without appropriate amount of anti-CCR5 antibody. Thus

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the artisan would have expected equal success using the anti-CCR5 antibody bound to CCR5 as 100% binding.

Therefore, the reference clearly suggests the claimed invention.

8b. Claim 9 is rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent No. 6,528,625 ('625 patent).

This rejection is maintained for reasons of record set forth at page 4 of the previous Office action (1/22/2007).

Applicants argue that the '635 patent does not disclose or suggest such a method for measuring an occupying ratio of a compound bound to a strong binding site of CCR5 and that in general, the ligand bound to the receptor is dissociated with a lapse of time. However, contrary to Applicants arguments, since the recitation of the term "strong binding site" is unclear, the reference anticipates the claim because the reference describes a method of identifying and detecting ligands bound to a CCR5 expressing cell by allowing a CCR5 expressing cell to contact with a compound to be tested allowing the compound to bind, then contacting with labeled anti-CCR5 antibody and calculating the binding ratio of the compound bound to CCR5 based on the amount of compound bound in the presence and absence of labeled anti-CCR5 antibody (see column 3, lines 32-67; column 4, lines 1-14). The reference teaches using an anti-CCR5 antibody, which binds to CCR5 and competes against the compound for the binding site of CCR5. It would be *prima facie* obvious to one of ordinary skill in the art to measure the occupying ratio of the compound bound to CCR5 on the cell based on the ratio of the bound amount of labeled anti-CCR5 antibody when the compound is bound to CCR5 to a bound



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amount of labeled anti-CCR5 antibody when the compound is not bound to CCR5. One of ordinary skill in the art would have been motivated to do so because the reference teaches that this assay can be used to detect agents including ligands or other substances including inhibitors or promoters of receptor function which can bind CCR5 (see column 4, lines 3-14).

Therefore, the reference clearly suggests the claimed invention.

### ***Conclusion***

No claim is allowed.

Claims 9, 33 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

### ***Advisory Information***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Prema Mertz Ph.D., J.D.

Primary Examiner

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August 8, 2007